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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,056	10/13/1999	ROGER CAROLUS AUGUSTA EMBRECHTS	JAB-1267	6783

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/403,056

Applicant(s)

Embrechts

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 5, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The request for the extension of time and amendment filed on 6-5-02 are acknowledged.

Claims included in the prosecution are 1-19.

Claim Rejections - 35 U.S.C. § 103

1. **The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu (5,456,851), Mason (5,536,742) individually or in combination, further in combination with Fost (5,688,496), (5,648,348) and Vanmiddlesworth (5,164,375).**

Liu discloses shampoo formulations containing the various additives and ketonazole as the active ingredient; Liu also discloses that ketonazole is an anti-fungal agent and is useful for the treatment of psoriasis and seborrheic dermatitis (note the abstract, columns 1-4, Examples and claims).

Mason similarly discloses shampoo preparations containing ketonazole, econazole or miconazole for the treatment of seborrhoea. Mason notes the association of this disease with yeast (fungus) (note the abstract, columns 1-2 and claims).

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What is lacking in the above references is the inclusion of a phospholipid in the shampoo preparations.

Fost (496) while disclosing skin and hair care compositions including shampoos containing synthetic phospholipids teaches the excellent properties of phospholipids such as foaming, viscosity building, wetting, cleansing, detergency and conditioning which makes them very useful (note the abstract, col.1, line 18 through col. 2, line 25, col. 6, line 54 et seq., columns 15-17, examples 16-18 and claims).

Fost (348) while disclosing various personal care products teaches that the synthetic phospholipids have excellent antifungal activity (note the abstract, columns 6-7, examples and claims).

VanMiddlesworth teaches that a synthetic phospholipid of his invention has antifungal activity (note the abstract).

The inclusion of a phospholipid in the shampoo compositions of Liu or Mason would have been obvious to one of ordinary skill in the art since the secondary references clearly teach the excellent properties of the phospholipids and also their anti-fungal activity.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant once again argues that Lie, and Mason do not teach phospholipids; the examiner agrees, but points out that the secondary references the use of phospholipids. Applicant argues that given the fact that the compositions of Liu and Mason already

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include an antifungal component, and no suggestion in either Liu or Mason to further include yet another antifungal compound, let alone the particular antifungal phospholipids are Frost or Vanmiddlesworth. This argument is not found to be persuasive since it is within the skill of the art to include two antifungal agents with a reasonable expectation of obtaining at least an additive effect (see *In re Kerhoven* 205 USPQ 1069). Applicant argues that the phospholipids in Fost 348 have a structure different from the phospholipids in Fost 496 and therefore, there is neither a disclosure nor a suggestion in Fost 348 to include its antifungal/antibacterial phospholipids. This argument is not found to be persuasive since the references of Fost clearly indicate the advantages of using phospholipids in personal care products and indeed as recognized by applicant himself, one of the phospholipids taught by Fost has these properties and furthermore, the phospholipid taught by Vanmiddlesworth has these properties. Applicant's arguments that Fost does not teach phospholipid of instant claim 3 are not found to be persuasive since this is an art known phospholipid and one of ordinary skill in the art would use a known phospholipid with a reasonable expectation of success. With regard to the synergistic properties argued:- as already pointed out before, a close examination of the results on page 15 of the specification appear to indicate no controls with the antifungal agent or the phospholipids by themselves were performed and no statistical significance of the results has been presented. The examiner points out that scope of the claims is not commensurate with the

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synergistic effect observed in terms of generic 'antifungal' and phospholipid and in terms of organisms.

3. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu (5,456,851), Mason (5,536,742) individually or in combination, further in combination with Fost (5,688,496), (5,648,348) and Vanmiddlesworth (5,164,375) as set forth above, further in view of GB 22 56 139.

The teachings of Liu, Mason, Fost and Vanmiddlesworth have been discussed above.

GB while disclosing emulsions containing terbinafine and phospholipids, teaches that such a combination results in enhanced efficacy of the compound (note the abstract, page 2, 4 and examples; example 3 in particular).

One of ordinary skill in the art would be motivated further to use phospholipids together with the antifungal compounds in view of the enhanced efficacy of antifungal agents taught by GB.

Applicant provides no specific arguments for this rejection and hence, the rejection is maintained.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

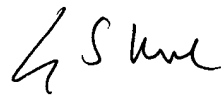
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

August 19, 2002